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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-365]

Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Established Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2013

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice.

SUMMARY: This notice establishes the initial 2013 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

EFFECTIVE DATE: [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 307-4654.

SUPPLEMENTARY INFORMATION: Section 306 of the CSA (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been

delegated to the Administrator of the DEA by 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator pursuant to 28 CFR 0.104.

The 2013 aggregate production quotas and assessment of annual needs represent those quantities of schedule I and II controlled substances and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in the United States in 2013 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine but do not include imports of controlled substances for use in industrial processes.

On August 3, 2012, a notice titled, "Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Proposed Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2013," was published in the Federal Register (77 FR 46519). That notice proposed the 2013 aggregate production quotas for each basic class of controlled substance listed in schedules I and II and the 2013 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. All interested persons were invited to comment on or object to the proposed aggregate production quotas and the proposed assessment of annual needs on or before September 4, 2012.

Five comments (four from DEA-registered manufacturers and one from a non-registrant) were received within the published comment period, offering comments on a total of 20 schedule I and II controlled substances and one list I chemical. Commenters stated that the proposed aggregate production quotas for amphetamine (for conversion),

amphetamine (for sale), codeine (for conversion), codeine (for sale), gamma hydroxybutyric acid, hydrocodone (for sale), hydromorphone, lisdexamfetamine, meperidine, methamphetamine, methylphenidate, morphine (for conversion), morphine (for sale), noroxymorphone (for conversion), oripavine, oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), remifentanil, and sufentanil were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. One commenter stated that the proposed assessment of annual needs quota for phenylpropanolamine (for conversion) was insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks.

In determining the 2013 aggregate production quotas and assessment of annual needs, DEA has taken into consideration the above comments along with the factors set forth at 21 CFR 1303.11 and 21 CFR 1315.11, in accordance with 21 U.S.C. 826(a), and other relevant factors, including the consideration of 2012 manufacturing quotas, current 2012 sales and inventories, 2013 export requirements, industrial use, additional applications for quotas, as well as information on research and product development requirements. Based on this information, DEA has determined that adjustments to the proposed aggregate production quotas and assessment of annual needs for 3,4-methylenedioxy-N-methylcathinone (methylone), 3,4,methylenedioxypyrovalerone (MDPV), 4-methyl-N-methylcathinone (mephedrone), N-benzylpiperazine, amphetamine (for conversion), amphetamine (for sale), hydrocodone (for sale), hydromorphone, lisdexamfetamine, methylphenidate, morphine (for sale), oxycodone (for sale), oxymorphone (for conversion), remifentanil, sufentanil, tapentadol, ephedrine (for

conversion), ephedrine (for sale), phenylpropanolamine (for sale), and pseudoephedrine (for sale) are warranted. This notice reflects those adjustments.

Regarding codeine (for conversion), codeine (for sale), gamma hydroxybutyric acid, meperidine, methamphetamine, morphine (for conversion), noroxymorphone (for conversion), oripavine, oxymorphone (for sale), and phenylpropanolamine (for conversion), DEA has determined that the proposed initial 2013 aggregate production quotas and assessment of annual needs are sufficient to meet the current 2013 estimated medical, scientific, research, and industrial needs of the United States. This notice finalizes these aggregate production quotas at the same amounts as proposed.

DEA also specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. See 21 CFR 1303.24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, DEA included in all schedule II aggregate production quotas, and certain schedule I aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The established aggregate production quotas reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate

public need, as determined by DEA. DEA does not anticipate utilizing the reserve in the absence of these circumstances.

In accordance with 21 U.S.C. 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Deputy Administrator hereby establishes the 2013 aggregate production quotas for the following schedule I and II controlled substances and the 2013 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class – Schedule I	Established 2013 Quotas
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45 g
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45 g
1-[1-(2-Thienyl)cyclohexyl]piperidine	5 g
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8)	45 g
1-Hexyl-3-(1-naphthoyl)indole (JWH–019)	45 g
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45 g
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH–203)	45 g
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250)	45 g
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398)	45 g
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122)	45 g
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19, RCS–4)	45 g
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081)	45 g
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P)	15 g
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	15 g
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	15 g
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	15 g
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	15 g
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	15 g
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	15 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	12 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	12 g
2,5-Dimethoxyamphetamine	12 g
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	15 g
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	15 g
3,4,5-Trimethoxyamphetamine	12 g
3,4 Methylenedioxyamphetamine (MDA)	30 g

3,4-Methylenedioxymethamphetamine (MDMA)	35 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	24 g
3,4-Methylenedioxy-N-methylcathinone (methylone)	35 g
3,4-Methylenedioxypyrovalerone (MDPV)	25 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	12 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	12 g
4-Methoxyamphetamine	88 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	12 g
4-Methylaminorex	12 g
4-Methyl-N-methylcathinone (mephedrone)	25 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47, 497 C8-homolog)	53 g
5-Methoxy-3,4-methylenedioxyamphetamine	12 g
5-Methoxy-N,N-diisopropyltryptamine	12 g
5-Methoxy-N,N-dimethyltryptamine	10 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	12 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	12 g
Aminorex	12 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	12 g
Codeine-N-oxide	602 g
Desomorphine	5 g
Diethyltryptamine	12 g
Difenoxin	50 g

Dihydromorphine	3,300,000 g
Dimethyltryptamine	18 g
Gamma-hydroxybutyric acid	46,250,000 g
Heroin	25 g
Hydromorphinol	54 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	30 g
Marihuana	21,000 g
Mescaline	13 g
Methaqualone	10 g
Methcathinone	14 g
Methyldihydromorphine	2 g
Morphine-N-oxide	655 g
N,N-Dimethylamphetamine	12 g
N-Benzylpiperazine	15 g
N-Ethylamphetamine	12 g
N-Hydroxy-3,4-methylenedioxyamphetamine	12 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Properidine	2 g
Psilocybin	2 g
Psilocyn	4 g
Tetrahydrocannabinols	491,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

Basic Class – Schedule II	Established 2013 Quotas
1-Phenylcyclohexylamine	3 g
1-Piperdinocyclohexanecarbonitrile	21 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,250,000 g
Alfentanil	38,250 g
Alphaprodine	3 g
Amobarbital	9 g
Amphetamine (for conversion)	22,875,000 g
Amphetamine (for sale)	42,625,000 g

Carfentanil	6 g
Cocaine	240,000 g
Codeine (for conversion)	81,250,000 g
Codeine (for sale)	49,506,250 g
Dextropropoxyphene	19 g
Dihydrocodeine	250,000 g
Diphenoxylate	750,000 g
Ecgonine	127,500 g
Ethylmorphine	3 g
Fentanyl	2,108,750 g
Glutethimide	3 g
Hydrocodone (for sale)	99,625,000 g
Hydromorphone	5,968,750 g
Isomethadone	5 g
Levo-alphacetylmethadol (LAAM)	4 g
Levomethorphan	6 g
Levorphanol	4,500 g
Lisdexamfetamine	21,000,000 g
Meperidine	6,875,000 g
Meperidine Intermediate-A	6 g
Meperidine Intermediate-B	11 g
Meperidine Intermediate-C	6 g
Metazocine	6 g
Methadone (for sale)	25,000,000 g
Methadone Intermediate	32,500,000 g
Methamphetamine	3,912,500 g
[987,500 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product**;** 2,863,750 grams for methamphetamine mostly for conversion to a schedule III product; and 61,250 grams for methamphetamine (for sale)]	
Methylphenidate	80,750,000 g
Morphine (for conversion)	103,750,000 g
Morphine (for sale)	60,250,000 g
Nabilone	25,628 g
Noroxymorphone (for conversion)	9,000,000 g
Noroxymorphone (for sale)	508,750 g
Opium (powder)	91,250 g
Opium (tincture)	1,287,500 g
Oripavine	22,750,000 g
Oxycodone (for conversion)	10,250,000 g
Oxycodone (for sale)	131,500,000 g
Oxymorphone (for conversion)	18,375,000 g
Oxymorphone (for sale)	6,875,000 g

Pentobarbital	42,500,000 g
Phenazocine	6 g
Phencyclidine	30 g
Phenmetrazine	3 g
Phenylacetone	20,000,000 g
Racemethorphan	3 g
Remifentanil	3,750 g
Secobarbital	215,003 g
Sufentanil	6,255 g
Tapentadol	13,750,000 g
Thebaine	145,000,000 g

Basic Class – List I Chemicals	Established 2013 Quotas
Ephedrine (for conversion)	15,100,000 g
Ephedrine (for sale)	3,500,000 g
Phenylpropanolamine (for conversion)	25,700,000 g
Phenylpropanolamine (for sale)	6,100,000 g
Pseudoephedrine (for sale)	225,000,000 g

The Deputy Administrator also establishes aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 at zero. Pursuant to 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Deputy Administrator may adjust the 2013 aggregate production quotas and assessment of annual needs as needed.

__September 25, 2012_____

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Dated:

Thomas M. Harrigan,
Deputy Administrator

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